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Appendix 2

OCT - 6 2006

5. 510(k) Summary (Revised)

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R 807.92.
Submitter	Ceres Medical Systems, L.L.C. 4665 Sweetwater Blvd., Suite 104 Sugar, Land, TX 77479
Contact Person	Corrine Bonfiglio, RAC Tel: (858) 481-1638 Fax: (858) 481-2363 Mobile: (858) 342-0344 E-mail: cbonfiglio@meister.net
Date Prepared	September 26, 2006
Trade Name	Ceres PTA Catheter
Common Name	Percutaneous Transluminal Angioplasty (PTA) Catheter
Classification Name	Percutaneous Catheter (21 CFR 870.1250, Product Code DQY)
Predicate Device	The Ceres PTA Catheter manufactured by JOMED AG which was cleared for market entry on April 11, 2002 under 510(k) #K020854.
Description	The Ceres PTA catheter is a single-use, sterile balloon dilation catheter for angioplasty. A double lumen coaxial shaft features an inflatable balloon at its distal end. The proximal end provides a double hub connector, whose first port allows the attachment of an inflatable device which is used to inflate and deflate the balloon through the outer lumen. A second hub port allows the advance of a guidewire throughout the entire length of the catheter using the distally open inner lumen. Platinum radiopaque bands are used to locate the balloon under fluoroscopy.
Indications for Use	The Fox Plus PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries and native or synthetic arteriovenous dialysis fistulae.
Substantial Equivalence	The Ceres PTA catheter is substantially equivalent to the Fox Plus PTA catheter because the indications for use are identical and the function, design and performance specifications are comparable.
Non-clinical Performance	Non-clinical testing was conducted to confirm the safe and effective performance of the Ceres PTA catheter. Non-clinical testing also demonstrated the biocompatibility of the subject device.
Conclusion	The Ceres PTA catheter is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2006

Ceres Medical Systems L.L.C.
c/o Ms. Corrine M. Bonfiglio
13195 Seagrove Street
San Diego, CA 92130

Re: K060927
Ceres PTA Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: DQY
Dated: September 26, 2006
Received: September 27, 2006

Dear Ms. Bonfiglio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 1

4. Indications for Use Statement (Revised)

510(k) Number (if known): K060927

Device Name: Ceres PTA Catheter

Indications for Use:

The Ceres PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries and native or synthetic arteriovenous dialysis fistulae.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mc...

Division Sign-Off

...Cardiovascular Devices

510(k) Number K060927

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(Posted November 13, 2003)